

CLAIMS

1. A device for maintaining pressure onto a blood vessel, comprising:
  - a) a tissue-confining device having two parallel longitudinally extending bars which extend between a proximal end and a distal end;
  - b) at least one strap attachable to tissue in the vicinity of the blood vessel, for retaining said tissue-confining device in compressing contact with tissue in the vicinity of the blood vessel; and
  - c) means for affixing said at least one strap to an element connected to said tissue-confining device.
2. Device according to claim 1, wherein the tissue-confining device has an open area bounded by spaced apart longitudinally extending bars and at least one connecting bar.
3. Device according to claim 1, which is a post-hemostasis pressure maintaining device such that the tissue-confining device is positioned in the vicinity of a sealed puncture site, the at least one strap being adapted for retaining said tissue-confining device in sufficient compressing contact with tissue in the vicinity of a blood vessel so as to maintain sealing of the puncture site.
4. Device according to claim 1, further comprising means for applying a tensile force to the at least one strap.

5. Device according to claim 4, wherein the tensile force applying means comprises a piston assembly.
6. Device according to claim 5, wherein the piston assembly comprises:
- a) a stationary cylinder having a sealing element on the upper end thereof, said cylinder attached to, or integrally formed with, a lower plate connected to the longitudinal bars of tissue-confining device;
  - b) a tubular sleeve formed integrally with an upper plate and protruding therethrough, at least one strap being secured to said upper plate; and
  - c) a unilateral valve seated in a neck formed at the upper end of said sleeve,
- wherein said sleeve is adapted to be fitted about said cylinder such that the interior volume of said sleeve between said unilateral valve and said sealing element constitutes a pressure chamber, the pressure differential between the interior and exterior of said pressure chamber which is generated following introduction therein of a fluid via said unilateral valve being sufficient to displace said sleeve and upper plate vertically upwardly relative to said cylinder, thereby applying a tensile force to the at least one strap.
7. Device according to claim 4, wherein the tensile force applying means comprises:
- a) a planar balloon-supporting frame positioned above the tissue-confining device;
  - b) a plurality of posts connecting said frame and the two longitudinally

extending bars of the tissue-confining device;

- c) a pad secured to said frame on top of which a balloon is placed; and
  - d) at least one strap adhered to said balloon and to skin in the vicinity of a sealed puncture site, said at least one strap being tensed upon outward expansion of said balloon, whereby to retain the tissue-confining device in compressing contact with tissue in the vicinity of the blood vessel.
8. Device according to claim 7, wherein the balloon is expanded by a syringe in communication with a tube connected to the balloon.
9. Device according to claim 1, further comprises means for applying axial pressure onto the blood vessel.
10. Device according to claim 9, wherein the means for applying axial pressure onto the blood vessel is plunger connected to a rod extending from the tissue-confining device, said plunger being engageable with the blood vessel as the tissue-confining device is brought to compressing contact with the tissue in the vicinity of the blood vessel.
11. Device according to claim 8, wherein the means for applying axial pressure onto the blood vessel comprises means for applying wide-area axial pressure.
12. Device according to claim 11, wherein the means for applying extended, wide-area axial pressure onto the blood vessel is an intermediate plate which is

fixedly positioned above the tissue-confining device and a syringe-inflatable balloon placeable on the blood vessel and below said intermediate plate, upward expansion of said balloon being restrained by said intermediate plate so as to apply wide-area axial pressure to the blood vessel.

13. Device according to claim 12, wherein the intermediate plate is positioned above the tissue-confining device by means of two posts connecting the two longitudinally extending bars of the tissue-confining device, respectively, and the intermediate plate.
14. Device according to claim 11, the means for applying extended, wide-area axial pressure onto a sealed puncture site is a lower plate which is wider than the gap between, and connected to, the two bars of the tissue-confining device, wherein subcutaneous tissue confined between the bars of the tissue-confining device projects sufficiently upwardly upon application of manual axial pressure onto the tissue-confining device so as to be pressed by said lower plate and to maintain sealing of the puncture site.
15. Device according to claim 11, the means for applying extended, wide-area axial pressure onto a sealed puncture site is a pad secured to opposed longitudinally extending bars of the tissue-confining device.
16. Device according to claim 12 or 14, further comprising a handle connected to a plate, by which manual axial pressure is transmitted to the tissue-confining

device.

17. Device according to claim 16, wherein the handle is an upper plate larger than, and connected to plate by which manual axial pressure is transmitted to the tissue-confining device.
18. Device according to claim 1, wherein axial pressure is applied onto the tissue-confining device by means of an artery clamp apparatus.
19. Device according to claim 1, wherein the artery clamp apparatus is adjustable and the tissue-confining device is detachable from said adjustable artery clamp apparatus.
20. Device according to claim 1, wherein manual axial pressure is transmitted to the tissue-confining device by means of an element connected directly or indirectly to the tissue-confining device.
21. Device according to claim 1, wherein the affixing means comprises proximal and distal strap assemblies which are attached to the proximal and distal ends, respectively, of the tissue-confining device.
22. Device according to claim 21, wherein each strap assembly comprises means for angularly displacing at least one strap.

23. Device according to claim 21, wherein each strap assembly comprises means for axially displacing at least one strap.
24. Device according to claim 23, wherein the angularly displacing means comprises an axially extending member in fixed relationship with the tissue-confining device by means of a connecting element detachably connected to the tissue-confining device; and an element affixed to said at least one strap which is rotatably attached to said axially extending member and supported by an abutment plate provided with the axially extending member.
25. Device according to claim 24, wherein the axially extending member is a bolt which is threadedly engageable with an internally threaded bolt support connected to, or integral with, the connecting element.
26. Device according to claim 24, wherein the pressure by which the at least one strap adheres to tissue is adjustable upon lowering or raising the abutment plate by means of the bolt, with the at least one strap remaining at substantially the same angle with respect to the bolt support.
27. Device according to claim 24, wherein the axially displaceable member is axially displaceable by hydraulic or pneumatic means.
28. Device according to claim 21, wherein each strap assembly comprises a U-shaped element having two mutually parallel, longitudinally extending legs; a

connector attached to one of said legs; and an L-shaped element connected at one end to said connector and detachably connected at the other end thereof to the longitudinally extending bar.

29. Device according to claim 28, wherein a strap is securable to a corresponding leg of the U-shaped element.
30. Device according to claim 21, wherein a pair of straps is attachable to a corresponding strap assembly, each strap being wrapped around a different periphery of the limb and connected together by an attachment means.
31. Device according to claim 1, wherein the affixing means comprises at least one track element connected to a rod extending from the tissue-confining device, a strap being translatable and angularly displaceable upon engagement with a corresponding track element.
32. Device according to claim 31, wherein the affixing means further comprises a U-shaped bracket for receiving a strap through a groove formed in a base thereof, each leg of said bracket being connected to a corresponding track element at a selected transversal distance from a bar of the tissue-confining device.
33. Device according to claim 1, wherein the affixing means comprises a bracket connected to the tissue-confining device, at least one strap assembly being

attached to, and being angularly displaceable with respect to, said bracket.

34. Device according to claim 33, wherein a strap assembly is attached to the bracket by a pin joint.
35. Device according to claim 33, wherein a strap assembly is releasably attached to the bracket by a pin vertically protruding from the bracket.
36. Device according to claim 33, wherein the bracket is U-shaped.
37. Device according to claim 36, wherein a first strap is engaged with a base of the bracket which is transversally spaced from the tissue-confining device and second and third straps are engaged with legs of the bracket, respectively, which are positioned closer to the tissue-confining device than said base.
38. Device according to claim 1, wherein the affixing means comprises a plate positioned vertically above the tissue-confining device, for receiving two opposed straps in corresponding grooves formed within the plate.
39. Device according to claim 38, wherein two posts axially extend from the plate to the proximal and distal ends, respectively, of the tissue-confining device.
40. Device according to any of claims 31 to 39, wherein each strap is insertable into a corresponding groove and foldable, whereby to define two strap

portions, the inner face of each strap portion being provided with adhesive material.

41. Device according to claim 1, wherein the affixing means comprises a plate positioned vertically above the tissue-confining device which is formed with two apertures, in each of which a different region of a strap is inserted and thereby secured to said plate.
42. Device according to claim 1, which is a post-pseudoaneurysm closure maintaining device and the tissue-confining device is positioned in the vicinity of a closed pseudoaneurysm neck, the at least one strap being adapted for retaining said tissue-confining device in sufficient compressing contact with tissue in the vicinity of the closed pseudoaneurysm neck so as to maintain closure thereof.
43. Device according to claim 1, which is an artery occluding device and the tissue-confining device is positioned in the vicinity of a burst artery wall, total occlusion of the artery being induced by both a proximal plunger positioned adjacent to the proximal end of the tissue-confining device and by axial pressure being applied onto the burst artery wall, the at least one strap being adapted for retaining said tissue-confining device in sufficient compressing contact with tissue in the vicinity of said burst artery wall so as to maintain conglutination of fragmented portions of said burst artery.

44. A dual hemostasis and post-hemostasis pressure maintaining device, comprising:

- a) a tissue-confining device having two parallel longitudinally extending bars which extend between a proximal end and a distal end;
- b) means for applying sufficient axial pressure onto said tissue-confining device for inducing hemostasis at a puncture site of a blood vessel;
- c) at least one strap attachable to tissue in the vicinity of said puncture site, for retaining said tissue-confining device in sufficient compressing contact with tissue in the vicinity of said puncture site following release of said hemostasis-inducing axial pressure so as to maintain post-hemostasis of said blood vessel;
- d) means for affixing said at least one strap to an element connected to said tissue-confining device; and
- e) optionally, means for applying a tensile force to the at least one strap.

45. Device according to claim 44, further comprising means for applying axial pressure onto the puncture site.

46. Device according to claim 45, wherein the means for applying axial pressure onto the puncture site is a plate connected to the two bars of the tissue-confining device and a handle connected to said plate.

47. Device according to claim 46, wherein the plate is adapted to sufficiently press subcutaneous tissue confined between the bars of the tissue-confining device

and projecting upwardly, upon application of the axial pressure onto the tissue-confining device, so as to induce hemostasis.

48. Device according to claim 46, wherein axial pressure is transmitted to the puncture site by means of an inflatable balloon placeable on the punctured blood vessel and beneath the plate which is connected to the bars of the tissue-confining device, upward expansion of the balloon being restrained by the plate so as to apply wide-area axial pressure to the punctured blood vessel and to facilitate inducement of hemostasis.
49. Device according to claim 45, wherein the means for applying axial pressure onto the puncture site for inducing hemostasis is also used for maintaining post-hemostasis pressure.
50. Device according to claim 45, wherein axial pressure is applied onto the tissue-confining device by means of an adjustable artery clamp apparatus, the tissue-confining device being detachable from said adjustable artery clamp apparatus following inducement of hemostasis.
51. Device according to claim 44, further comprising a proximal plunger which is releasably attachable to the proximal end of the tissue-confining device.
52. A method for maintaining pressure onto a blood vessel, comprising:
- a) providing a pressure maintaining device which comprises a tissue-confining

device having two parallel bars; at least one strap attachable to tissue in the vicinity of a blood vessel, for retaining said tissue-confining device in compressing contact with tissue in the vicinity of the blood vessel; and means for affixing said at least one strap to an element connected to said tissue-confining device;

- b) positioning said tissue-confining device in the vicinity of a blood vessel such that said blood vessel is substantially parallel to, and interposed between, said bars; and
- c) applying axial pressure onto said tissue-confining device by said at least one strap.

53. Method according to claim 52, further comprising the step of applying a tensile force to the at least one strap.

54. Method according to claim 53, wherein the tensile force is applied by the steps of:

- a) providing a planar frame positioned above the tissue-confining device and a pad secured to said frame;
- b) placing a balloon on top of said pad;
- c) adhering a balloon to at least one strap additionally adhered to skin in the vicinity of the blood vessel; and
- d) inflating said balloon such that outward expansion of said balloon is restrained by said at least one strap so as to apply axial pressure to the tissue-confining device.

55. Method according to claim 52, wherein the tensile force is applied by the steps of:

- a) providing a pressure chamber defined by the interior volume of a tubular sleeve between a unilateral valve seated in a neck of said sleeve and a stationary circular sealing element in contact with the inner wall of said sleeve;
- b) securing at least one strap to an upper plate integrally formed with said sleeve;
- c) attaching said at least one strap to tissue in the vicinity of the blood vessel; and
- d) introducing fluid into said pressure chamber via said unilateral valve such that the pressure differential between the interior and exterior of said pressure chamber is sufficient to displace said sleeve and said upper plate vertically upwardly relative to said sealing element, thereby applying a tensile force to said at least one strap.

56. Method according to claim 52, further comprising the step of applying axial pressure onto the blood vessel by an element secured to the tissue-confining device.

57. Method according to claim 52, wherein axial pressure is applied onto the tissue-confining device by affixing the at least one strap to the element connected to the tissue-confining device and adhering the at least one strap

to tissue in the vicinity of the blood vessel.

58. Method according to claim 52, wherein the pressure maintaining device is a post-hemostasis pressure maintaining device and the tissue-confining device is positioned in the vicinity of a sealed puncture site, whereby the tissue-confining device maintains hemostasis of said sealed puncture site.
59. Method according to claim 52, wherein the blood vessel is a superficial vein.
60. Method according to claim 59, wherein the blood vessel is the large saphenous vein and the tissue-confining device is positioned in the vicinity of a corresponding portion of the large saphenous vein, whereby sufficient axial pressure is applied onto said tissue-confining device for ensuring vein closure.
61. Method according to claim 60, wherein a plurality of tissue-confining devices are positioned along the length of the large saphenous vein.
62. Method according to claim 52, wherein the blood vessel is a burst artery and the tissue-confining device is positioned in the vicinity of a burst artery wall, whereby the at least one strap retains the tissue-confining device in sufficient compressing contact with tissue in the vicinity of said burst artery wall so as to maintain conglutination of fragmented portions of said burst artery.

63. Method according to claim 62, wherein total occlusion of the artery is induced by both a proximal plunger positioned adjacent to the proximal end of the tissue-confining device and by axial pressure applied onto the burst artery wall.
64. Method according to claim 52, wherein the pressure maintaining device is a post-pseudoaneurysm closure maintaining device and the tissue-confining device is positioned in the vicinity of a closed pseudoaneurysm neck, whereby the tissue-confining device maintains closure of said pseudoaneurysm neck.
65. A method for inducing hemostasis, comprising:
- a) providing a hemostasis inducing device which comprises a tissue-confining device having two parallel bars, a plate connected to said two bars, and a handle connected to said plate;
  - b) positioning said tissue-confining device in the vicinity of a punctured blood vessel such that said blood vessel is substantially parallel to, and interposed between, said bars; and
  - c) applying axial pressure onto said tissue-confining device by said handle, whereby sufficient axial pressure is applied by means of said plate onto said punctured blood vessel so as to induce hemostasis.
66. Method according to claim 65, wherein subcutaneous tissue confined

between the bars of the tissue-confining device projects sufficiently upwardly upon application of the axial pressure onto the tissue-confining device so as to be pressed by the plate and to induce hemostasis.

67. Method according to claim 65, further comprising the steps of:

- d) following the positioning of the tissue-confining device, placing a syringe-inflatable balloon on the punctured blood vessel and beneath the plate which is connected to the bars of the tissue-confining device; and
- e) following application of axial pressure onto the tissue-confining device by the handle, inflating said balloon whereby upward expansion thereof is restrained by said plate so as to apply wide-area axial pressure to the punctured blood vessel and to facilitate inducement of hemostasis.